

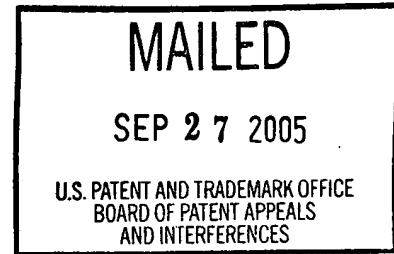
The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte NAOSUKE MARUYAMA

Appeal No. 2005-1746
Application No. 09/963,738



ON BRIEF

Before WILLIAM F. SMITH, MILLS, and GREEN, Administrative Patent Judges.
GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-21. Claims 1 and 21 are representative of the subject matter on appeal, and read as follows:

1. A dry direct tabletting base material comprising low-substituted hydroxypropyl cellulose impregnated with a sugar or a sugar alcohol wherein the product resulting therefrom is dried, and wherein said low-substituted hydroxypropyl cellulose has a hydroxypropyl content in the range from 5 to 16% by weight.

21. The dry direct tableting base material as claimed in claim 1 wherein said low-substituted hydroxypropyl cellulose is in fibrous form.

The examiner relies upon the following references:

Koyanagi et al. (Koyanagi)	3,852,421	Dec. 03, 1974
Obara	6,380,381	Apr. 30, 2002
Shimizu et al. (Shimizu)	WO 98/53798	Dec. 03, 1998

Claims 1-20 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Shimizu and Koyanagi. In addition, claim 21 stand rejected under 35 U.S.C. § 103(a) as being obvious over the previous combination as further combined with Obara. After careful review of the record and consideration of the issues before us, we affirm.

DISCUSSION

Claims 1-20 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Shimizu and Koyanagi. As claims 1-20 stand or fall together, see Appeal Brief, page 3, we focus our analysis on the broadest claim, claim 1.

The first step in deciding patentability issues under 35 U.S. C. § 103 is determining what is being claimed. See Key Pharmaceuticals v. Hercon Laboratories Corp., 161 F.3d 709, 714, 48 USPQ2d 1911, 1915 (Fed. Cir. 1998). The preamble of claim 1 states that the composition is “[a] dry direct tableting base material.” “If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is ‘necessary to give life, meaning, and vitality’ to the claim, then the claim preamble should be construed as if in the balance of the claim.” Pitney Bowes Inc. v. Hewlett

Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999).

“Where . . . a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation.” Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

In this case, the preamble merely states the intended use of the claimed composition. The preamble’s statement that the composition is intended as “[a] dry direct tableting base material” does not add any further limitations to those recited in the body of the claim. “If the preamble adds no limitations to those in the body of the claim, the preamble is not itself a claim limitation and is irrelevant to proper construction of the claim.” IMS Technology, Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1434, 54 USPQ2d 1129, 1137 (Fed. Cir. 2000). Therefore, we interpret claim 1 as encompassing compositions comprising low-substituted hydroxypropyl cellulose impregnated with a sugar or a sugar alcohol wherein the product resulting therefrom is dried, and wherein said low-substituted hydroxypropyl cellulose has a hydroxypropyl content in the range from 5 to 16% by weight.

Turning now to the rejection, Shimizu is cited for teaching a solid preparation that “comprises a water-soluble sugar alcohol that may be selected as sorbitol and erythritol” and “a low-substituted hydroxypropyl cellulose.” Examiner’s Answer, page 4. Shimizu is also cited for teaching that a preferred dosage form is a tablet, which the examiner asserts “embraces the ‘dry direct

tableting” as required by claim 1. Id. The rejection states that “[t]he instant claims differ from the Shimuzu [] patent by claiming that the base material is for dry direct tableting.” Page 4.

Based on the panel’s construction of the claim, however, the fact that Shimuzu fails to specifically teach that the base material is for dry direct tableting is irrelevant, as Shimuzu teaches all of the components of the composition of claim 1, i.e., a low-substituted hydroxypropyl cellulose impregnated with a sugar or sugar alcohol, and thus would anticipate the composition of claim 1. Thus, we need not reach the teachings of Koyanagi, and as we find no error in the examiner’s conclusion that the subject matter of claim 1 is obvious, the rejection is affirmed.¹

Appellant argues that the instant claims require that the low-substituted hydroxypropyl cellulose be impregnated with a sugar or sugar alcohol, where, upon drying, the sugar or sugar alcohol exists inside the low-substituted hydroxypropyl cellulose. See Appeal Brief, page 4. Shimuzu, according to appellant, uses a fluidized bed granulator in Working Example 6 and others, which appellant asserts allows the sugar or sugar alcohol to attach only to the surface of the low-substituted hydroxypropyl cellulose. See id. Thus, appellant contends, the product of Shimizu is structurally different from the claimed product. See id.

¹ In fact, under the construction of the claim set forth here, claim 1 may in fact be anticipated by the Shimizu reference.

Appellant's arguments are not found to be convincing. Appellant's specification specifically teaches that:

According to one preferred process for preparing this base material for dry direct tableting obtained by impregnating low-substituted hydroxypropyl cellulose with a sugar or a sugar alcohol and then drying it, a wet granular material is prepared by dry-blending low-substituted hydroxypropyl cellulose with a sugar or sugar alcohol and then adding water to the resulting blend while agitating it, or by adding an aqueous solution of a sugar or a sugar alcohol to low-substituted hydroxypropyl cellulose while agitating it. Thereafter, the resulting granular material is dried in the usual manner, and may be pulverized and classified as required. Thus, the desired base material for dry direct tableting comprising low-substituted hydroxypropyl cellulose impregnated with a sugar or a sugar alcohol can be obtained. In addition to the above-described agitation granulation process, this base material may also be prepared by fluidized bed granulation, spray drying and other suitable processes.

Id. at 6-7 (emphasis added).

Shimizu teaches that

The solid preparation of the present invention can be produced in accordance with a conventional method in the fields of pharmaceutics. Such methods include, for instance, a method which comprises blending, if necessary after addition of water, a pharmaceutically active ingredient, a water-soluble sugar alcohol and low-substituted hydroxypropylcellulose having hydroxypropyl group contents of 7.0 to 9.9 percent by weight, and molding, if necessary followed by drying.

Id. at 14. Moreover, in Working Example 1, a fluidized bed granulator is used, in which granulation is carried out while spraying distilled water. See id. at 17.

Thus, the composition taught by Shimizu appears to be the same as that of the composition of claim 1, and the burden is shifted to appellant to demonstrate that they are different. See In re Best, 562 F.2d 1252, 1255, 195

USPQ 430, 433-34 (Fed. Cir. 1977). Arguments of counsel cannot take the place of evidence in the record. See In re Scarbrough, 500 F.2d 560, 566, 182 USPQ 298, 302 (CCPA 1974); In re DeBlauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

Appellant also contends that the declaration of Naosuke Maruyama submitted under 37 CFR § 1.132 "show that the product provided by Shimuzu has a lower flowability index as well as a longer disintegration time as compared to the base materials provided in Examples 1 through 4 of the present application." Appeal Brief, page 7.

Appellant's declaration is not deemed to be sufficient to overcome the rejection. The declaration refers to Examples 1-4 of the specification, which all appear to be limited to the use of a single type of low-substituted hydroxypropyl cellulose, LH-11, and thus are not commensurate in scope with the subject matter of claim 1, which is drawn to the use of any low-substituted hydroxypropyl cellulose, wherein said low-substituted hydroxypropyl cellulose has a hydroxypropyl content in the range from 5 to 16% by weight. See In re Peterson, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1383(Fed. Cir. 2003) ("the applicants' showing of unexpected results must be commensurate in scope with the claimed range). Finally, appellant has not explained how Comparative Example 2 represents the closest prior art, *i.e.*, Shimizu. For example, Shimizu's preferred low-substituted hydroxypropyl cellulose appears to be LH-32 (hydroxypropyl

group content of 8.8% by weight), whereas Comparative Example 2 uses LH-11. Thus, the declaration is not a comparison with the closest prior art.²

Claim 21 stands rejected under 35 U.S.C. § 103(a) as being obvious over the previous combination as further combined with Obara. As appellant argues only that Obara fails to supply the deficiencies of the previous rejection, see Appeal Brief, page 9, this rejection is also affirmed for the reasons set forth supra.

CONCLUSION

As the examiner has set forth a prima facie case of obviousness, the rejection is affirmed.

² Moreover, as Shimizu teaches all of the components of the composition of claim 1, and thus would appear to anticipate the claimed composition, and evidence of unexpected results may not be used to overcome an anticipatory reference.

No time period for taking any subsequent action in connection with this
Appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

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